SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Attorney's Office for the Eastern District of Wisconsin, and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the "United States"); Rikco International, doing business as Dr. Comfort (hereafter, "Dr. Comfort"); Rick I. Kanter, individually and as a principal of Dr. Comfort (hereafter, "Kanter"); and the Relators Matthew Snorek and David Schlageter ("Relators"). Collectively, all of the above will be referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

- A. At all relevant times, Dr. Comfort, a Wisconsin limited liability company, distributed, marketed, and sold diabetic shoes inserts in the United States, which were reimbursed by the federal Medicare program ("Medicare").
- B. At all relevant times, Rick I. Kanter owned at least a majority interest in Dr. Comfort.
- C. Matthew Snorek filed a *qui tam* action in the United States District Court for Eastern District of Wisconsin, captioned *United States of America ex rel. Matthew Snorek v. Ricko International, et al*, Case No. 06-C-386.
- D. David Schlageter filed a *qui tam* action in the United States District Court for the Eastern District of Wisconsin, captioned *United States of America ex rel. David*

Schlageter v. Rikco International LLC, Case No. 06-C-547.

- E. The *qui tam* actions identified in Paragraphs (C) and (D) will be referred to collectively as the "Civil Actions."
- F. The United States contends that Dr. Comfort and Kanter caused claims for payment for diabetic shoe inserts to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 1395kkk-1.
- G. The United States contends that it has certain civil claims, against Dr. Comfort and Kanter for engaging in the following conduct during the period from 2004 through 2006 (hereinafter referred to as the "Covered Conduct"):
 - Dr. Comfort sold custom diabetic shoe inserts that were not, in fact, custom as defined by Medicare because they were not created with a unique image of each foot; and
 - 2. Dr. Comfort sold heat moldable diabetic shoe inserts that did not comply with the Medicare requirements for those inserts and did not conform to the heat moldable diabetic inserts that Dr. Comfort submitted to Medicare for coding verification.
- H. The United States also contends that it has certain administrative claims against Dr. Comfort and Kanter for engaging in the Covered Conduct.
- I. This Agreement is neither an admission of liability by Dr. Comfort or Rick Kanter nor a concession by the United States that its claims are not well founded.
- J. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

K. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

- 1. Dr. Comfort and Kanter agree to pay to the United States \$27,000,000 (the "Settlement Amount"), and interest on the Settlement Amount at a rate of 2.125% from December 15, 2010 until April 11, 2011. Dr. Comfort and Kanter further agree to pay Relator Snorek's attorneys \$35,000 for their statuory fees and costs claim. The foregoing payments shall be made as specified in the following paragraphs.
- 2. Dr. Comfort and Kanter agree to pay the full Settlement Amount to the United States by electronic funds transfer pursuant to written instructions to be provided by United States Attorney's Office for the Eastern District of Wisconsin. Dr. Comfort and Kanter agree to make this electronic funds transfer no later than April 11, 2011.
 - a. Contingent upon the United States receiving the Settlement Amount from Dr. Comfort and Kanter and as soon as feasible after receipt, the United States agrees to pay \$797,394.82 to Relator Snorek and \$4,095,709.77 to Relator Schlageter by electronic funds transfer.
 - b. Dr. Comfort and Kanter agree to pay Relator Snorek's attorneys for their statutory fees and costs claim pursuant to electronic funds transfer to Snorek's counsel pursuant to written direction provided by Warren Benson Law Group. Dr. Comfort and Kanter agree to make this electronic funds transfer no later than April 11, 2011.

- 3. Subject to the exceptions in Paragraph 6 (concerning excluded claims), below, in consideration of the obligations of Dr. Comfort and Kanter in this Agreement, and conditioned upon Dr. Comfort and Kanter's full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Dr. Comfort and Kanter together with its current or former owners; officers, directors, affiliates, and employees; and the successors and assigns of any of them from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.
- 4. Subject to the exceptions in Paragraph 6 (concerning excluded claims), below, in consideration of the obligations of Dr. Comfort and Kanter in this Agreement, and conditioned upon Dr. Comfort and Kanter's full payment of the Settlement Amount, the Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, agree to release Dr. Comfort and Kanter, together with its current or former owners; officers, directors, affiliates, and employees; and the successors and assigns of any of them, from any civil monetary claim the Relators have or may have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.
- 5. In consideration of the obligations of Dr. Comfort in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Dr. Comfort, and conditioned upon Dr. Comfort's full payment of the Settlement Amount,

the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Dr. Comfort under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 6 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Dr. Comfort from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

- 6. Notwithstanding the releases given in paragraphs 3, 4, and 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:
 - a. Any civil, criminal, or administrative liability arising under Title
 26, U.S. Code (Internal Revenue Code);
 - b. Any criminal liability;
 - Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
 - d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct:

- e. Any liability based upon such obligations as are created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services; or
- g. Any liability for personal injury or property damage or for other consequential damages from the Covered Conduct.
- 7. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relators' receipt of the payment described in Paragraph 2, Relators and their heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its officers, agents, and employees from any claims arising from the filing of the Civil Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement or the Civil Actions.
- 8. Conditioned upon receipt of the payment described in Paragraph 2(b), the Relators for themselves, and for their heirs, successors, attorneys, agents, and assigns, agree to release Dr. Comfort, its officers, agents, and employees, and Kanter from any liability to the Relators arising from the filing of the Civil Actions, or under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs.
- 9. Relator Snorek, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release David Schlageter from any liability to Snorek arising from the filing of the Civil Actions, or under 31 U.S.C. § 3730(d) for expenses or attorney's

fees and costs. Relator Schlageter, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release Matthew Snorek from any liability arising from the filing of the Civil Actions, or under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs.

- 10. In compromise and settlement of the rights of OIG-HHS to exclude Kanter pursuant to 42 U.S.C. § 1320a-7(b)(7), based upon the Covered Conduct, Kanter agrees to be excluded under this statutory provision from Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f), for a period of fifteen (15) years. The exclusion shall be effective upon the Effective Date of this Agreement.
 - a. Such exclusion shall have national effect and shall also apply to all other federal procurement and nonprocurement programs. Federal health care programs shall not pay anyone for items or services, including administrative and management services, furnished, ordered, or prescribed by Kanter in any capacity while Kanter is excluded. This payment prohibition applies to Kanter and all other individuals and entities (including, for example, anyone who employs or contracts with Kanter and any hospital or other provider where Kanter provides services). The exclusion applies regardless of who submits the claim or other request for payment. Kanter shall not submit or cause to be submitted to any Federal health care program any claim or request for payment for items or services, including administrative and management services,

furnished, ordered, or prescribed by Kanter during the exclusion. Violation of the conditions of the exclusion may result in criminal prosecution, the imposition of civil monetary penalties and assessments, and an additional period of exclusion. Kanter further agrees to hold the Federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for items or services furnished, ordered, or prescribed to such beneficiaries or sponsors after the effective date of the exclusion. Kanter waives any further notice of the exclusion under and agrees not to contest such exclusion either administratively or in any state or federal court.

b. Reinstatement to program participation is not automatic. If Kanter wishes to be reinstated, Kanter must submit a written request for reinstatement to the OIG in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Such request may be made to the OIG no earlier than 120 days prior to the expiration of the minimum period of exclusion. Reinstatement becomes effective upon application by Kanter, approval of the application by the OIG, and notice of reinstatement by the OIG. Obtaining another license, moving to another state, or obtaining a provider number from a Medicare contractor, a state agency, or a Federal health care program does not reinstate Kanter's eligibility to participate in these programs.

- Comfort or Kanter may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.
- 12. Dr. Comfort and Kanter fully and finally release the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Dr. Comfort and/or Kanter have asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
- 13. Dr. Comfort and Kanter fully and finally release the Relators from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Dr. Comfort and Kanter have asserted, could have asserted, or may assert in the future against the Relators, related to the Covered Conduct and the Relators' investigation and prosecution thereof.
- 14. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any state payer, related to the Covered Conduct; and Dr. Comfort and

Kanter agree not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agree not to appeal any such denials of claims.

- 15. Dr. Comfort and Kanter agree to the following:
 - a. <u>Unallowable Costs Defined:</u> that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Dr. Comfort, Kanter, their present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "Unallowable Costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP):
 - (1) the matters covered by this Agreement and any related plea agreement;
 - (2) the United States' audit(s) and civil and criminal investigation of the matters covered by this Agreement;
 - (3) Dr. Comfort's and Kanter's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal investigation in connection with the matters covered by this Agreement

- (including attorney's fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment Dr. Comfort and Kanter make to the United
 States pursuant to this Agreement and any payments that
 Dr. Comfort and Kanter may make to Relators, including
 costs and attorneys fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
 - (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and
 - (ii) prepare and submit reports to the OIG-HHS.

However, nothing in this paragraph 15.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Dr. Comfort and Kanter. (All costs described or set forth in this Paragraph 15.a. are hereafter "Unallowable Costs.")

b. <u>Future Treatment of Unallowable Costs:</u> If applicable, these Unallowable Costs shall be separately determined and accounted for by Dr. Comfort and Kanter, and Dr. Comfort and Kanter shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request

submitted by Dr. Comfort or Kanter or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

Treatment of Unallowable Costs Previously Submitted for c. Payment: Dr. Comfort and Kanter further agree that within 90 days of the Effective Date of this Agreement they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Dr. Comfort, Kanter, or any of their subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Dr. Comfort and Kanter agree that the United States, at a minimum, shall be entitled to recoup from Dr. Comfort and Kanter any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the

United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Dr. Comfort, Kanter, or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Dr. Comfort, Kanter, or any of their subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Dr. Comfort's or Kanter's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 16. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity.
- 17. Upon receipt of the payments described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Actions a Notice of Intervention and Joint Stipulation of Dismissal with prejudice of the Civil Actions pursuant to Rule 41(a)(1).
- 18. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 19. Dr. Comfort and Kanter represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 20. The Relators represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
 - 21. This Agreement is governed by the laws of the United States. The Parties

agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the Eastern District of Wisconsin, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.

- 22. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.
- 23. This Agreement constitutes the complete agreement between the Parties.
 This Agreement may not be amended except by written consent of the Parties.
- 24. The individuals signing this Agreement on behalf of Dr. Comfort and Kanter represent and warrant that they are authorized by Dr. Comfort to execute this Agreement. The individual(s) signing this Agreement on behalf of the Relators represent and warrant that they are authorized by the Relators to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.
- 25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 26. This Agreement is binding on Dr. Comfort's and Kanter's successors, transferees, heirs, and assigns.
- 27. This Agreement is binding on the Relators' successors, transferees, heirs, and assigns.
- 28. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to)
the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall	1
constitute acceptable, binding signatures for purposes of this Agreement.	
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THE UNITED STATES OF AMERICA

DATED: 3/30/1/ BY: David I. Color

JOYCE R. BRANDA

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DATED: 3/5//11

BY:

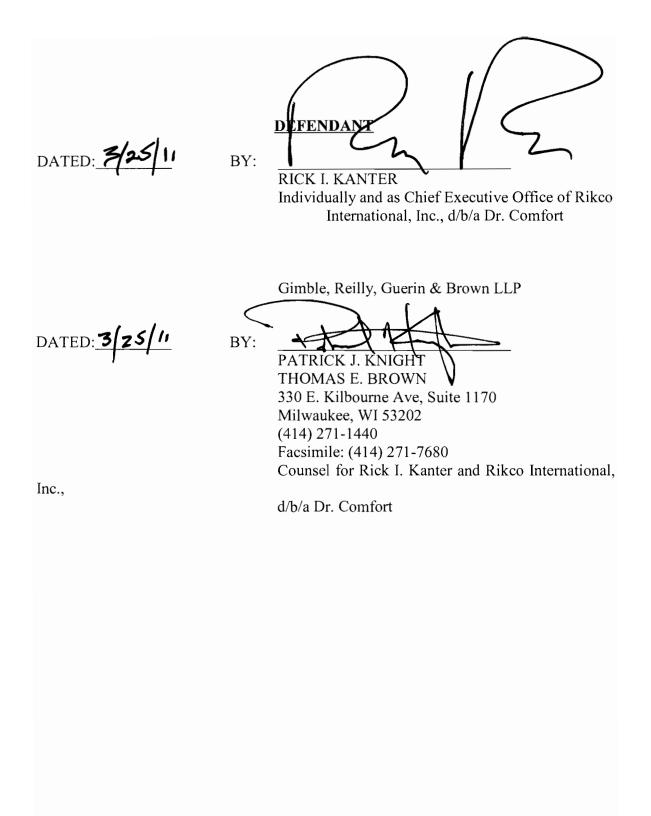
GREGORY E DEMSKE

Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General

Office of Inspector General

United States Department of Health and Human

Services



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DATED: 3-28-11	By		PHILLIA A. SWARER
		MATTHEW SNORE	K
DATED: 3/28/1/		175	
DATES -/ 2 8/11	BY:	PHILLIP E. BENSON	
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		Counsel for Matthew	Snorek
DATED:	BY:		
		DAVID SCHLAGETE	:R
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		RELATORS
DATED:	BY:	MATTHEW SNOREK
DATED:	BY:	PHILLIP E. BENSON Warren Benson Law Group 620 Newport Center Drive Suite 1100 Newport Beach, CA 92660 (949) 721-6636 Counsel for Matthew Snorek
dated: 3/28/1/	BY:	DAVID SCHLAGETER
DATED: <u>\$\big ^2-8\big 11</u>	BY:	FRANK R. TERSCHAN Terschan, Steinle & Ness 309 N Water St Ste 215 Milwaukee, WI 53202-5713 (414) 258-1010 Facsimile: (414) 258-8080 Counsel for David Schlageter